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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,170

02/27/2004

Alain Fouere

P24980

4885

7055 7590 05/07/2009
GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

NOTIFICATION DATE

DELIVERY MODE

05/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/787,170	Applicant(s) FOUERE ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

3DETAILED ACTION

This non-final action is in response to the Affirmance-in-Part rendered by the Board of Patent Appeals and Interferences on 3 February 2009. Prosecution is hereby reopened by the Examiner.

A Technology Center Director or designee has approved this Office Communication by signing below:

/DONALD HAJEC/

Director, Technology Center 3700

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8, 9, 11, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (6,629,533).

In the specification and figures, Webb et al. disclose a punctum plug and method for inserting the punctum plug in the lachrymal duct using an insertion tool. The punctum plug (110/210/310/410/510) has a body or shaft that is substantially cylindrical

with an axial bore therethrough for the passage of an insertion tool, and one or more flexible anchoring arms or elements attached to the external wall of the plug (see column 4, lines 7-45). The anchoring arms are constructed of a resilient material and are flexible enough to fold during the insertion procedure and then straighten out once in place. The anchoring arms function to retain the plug in the patient's punctum. As is shown in the figures, the anchoring arms may be in the shape of radial arms (or pins) and may be of the same length, different lengths, or varying lengths. The plug may have one or more disks. It is the position of the Examiner that the anchoring arms disclosed by Webb are equivalent to, or correspond to, Appellant's claimed pins, since the arms extend radially outward from the body in a helical formation, are of a constant length, and serve to reinforce & stabilize the apparatus within the punctum. The shape is seen to be in the form of a cone (see figures 2-7). The apparatus is made of flexible material. Webb et al. discloses a method of inserting the plug into the punctum using an insertion tool.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533).

In the specification and figures, Webb discloses the apparatus substantially as claimed with the exception of the anchoring pins disposed in the shape of a helix. Webb does disclose, however, a unitary anchoring member 338 in the shape of a helix (see FIG 4A). It has been held that forming in one piece an article that was previously formed in several pieces and joined together is an unpatentable variation on the prior art. See MPEP§ 2144.04(V)(A). In the instant case, the discrete pins placed together on the body of the plug serve the same retention function on the claimed apparatus as the solid helical retention arm disclosed by Webb. Accordingly, it is the position of the Examiner that the apparatus would have been an obvious variation on the Webb device.

5. Claims 10, 15, & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of MacKeen et al. (4,915,684). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, but fails to disclose specifically that the punctum plug has an axial duct for the passage of tears and that the insertion tool used for inserting the plug is a push rod.

MacKeen et al. discloses a punctum plug and a method for inserting the plug. The plug comprises a body that is substantially cylindrical and has an axial bore or duct for the passage of tears. MacKeen et al. teaches that an insertion tool that is a dilating rod (i.e. push rod) is used to insert the plug into the punctum (see figures 5A-E). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the plug of Webb et al. to include an open axial duct as taught by MacKeen et al.

to meter the passage of lacrimal fluid (or tears) away from the eye, through the punctum while the plug was inserted.

6. Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Freeman (3,949,750). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the insert is made of metal or shape memory metal. Freeman discloses a punctum plug that may be made of stainless steel or other inert metal material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of either stainless steel as taught by Freeman or to be made of or Nitinol (shape memory material), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Freeman discloses the use of metal for punctum plugs and it is well known in the art to use shape memory metals such as Nitinol, since both are well received by the body.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Herrick (5,163,959). Webb et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of a radio-opaque material that is visible with X-rays. Herrick discloses a canalicular implant that may be made of a material that is responsive to X-

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rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

8. Claims 16, 17, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Seder et al. (4,959,048). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the tool used to implant the plug includes jaws. Seder et al. discloses a lacrimal duct occluder and forceps for insertion of the occluder. A forceps is considered to have jaws. It would have been an obvious matter of design choice to modify the method of insertion of Webb et al. to substitute the forceps as the tool, as taught by Seder et al., since Appellant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
7 April 2009